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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK A/S and NOVO NORDISK INC., Plaintiffs, v. MAI KAGA, MD LLC a/k/a THE KAGA ACADEMY OF AESTHETIC & CONCIERGE MEDICINE, Defendant.	Civil Action No. 25-267

COMPLAINT

Plaintiffs Novo Nordisk A/S ("NNAS"), with a principal place of business at Novo Alle 1, 2880 Bagsvaerd, Denmark, and Novo Nordisk Inc. ("NNI"), with a principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536 (collectively, "Plaintiffs" or "Novo Nordisk"), by and through their undersigned attorneys, for their complaint for false advertising and unfair competition seeking injunctive and other relief against Defendant Mai Kaga, MD LLC a/k/a The Kaga Academy of Aesthetic & Concierge Medicine ("Defendant"), with a principal place of business at 320 Fordham Place, Freehold, New Jersey 07728, hereby allege as follows,

on actual knowledge with respect to themselves and their own acts, and on information and belief as to all other matters.

INTRODUCTION

1. Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases like diabetes and obesity.

2. The development of semaglutide is an example of Novo Nordisk's commitment to innovation for those living with chronic diseases. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's three prescription-only medicines approved by the Food and Drug Administration ("FDA"): Ozempic® (semaglutide) injection and Rybelsus® (semaglutide) tablets for adults with type 2 diabetes and Wegovy® (semaglutide) injection for chronic weight management.

3. Novo Nordisk is the only company in the United States with FDA-approved medicines containing semaglutide.

4. Novo Nordisk is also the only company authorized to identify its FDA-approved semaglutide medicines using the trademarks Ozempic®, Wegovy®, and Rybelsus®.

5. The FDA has not approved any generic versions of semaglutide medicines. To the contrary, the FDA has sent warning letters to companies that claimed that their Unapproved Products have the "same active ingredient as Ozempic, Rybelsus, and Wegovy," noting that Ozempic and Wegovy are the only "two injectable semaglutide products FDA-approved for the U.S. market."[1]

[1] U.S. FOOD & DRUG ADMIN., WARNING LETTER TO OZEMPEN.COM, MARCS-CMS 684435 (June 24, 2024), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ozempencom-684435-06242024.

6. This action is brought pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, related state laws, and the common law arising out of Defendant's acts of false advertising and unfair competition.

7. Defendant markets and sells to patients compounded drug products that purport to contain semaglutide.

8. Even though such compounded drug products have not been evaluated by the FDA for their safety, effectiveness, or quality, Defendant falsely and misleadingly represents to patients that its products are (1) FDA-approved, (2) as effective as Novo Nordisk's FDA-approved semaglutide medicines, and (3) equivalent to Novo Nordisk's FDA-approved semaglutide medicines.

9. Defendant's conduct is likely to confuse and deceive patients into mistakenly believing that they are purchasing authentic Novo Nordisk medicines or medicines that have been evaluated by the FDA, studied in clinical trials, and deemed safe and effective.

THE PARTIES

10. Plaintiff NNAS is a corporation organized and existing under the laws of the Kingdom of Denmark and has its principal place of business at Novo Alle 1, 2880 Bagsvaerd, Denmark.

11. Novo Nordisk developed the Ozempic®, Wegovy®, and Rybelsus® medicines.

12. NNAS has granted to NNI exclusive rights to market, advertise, promote, offer for sale, and sell Ozempic®, Wegovy®, and Rybelsus® medicines in the United States.

13. NNI is a corporation organized and existing under the laws of Delaware and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

14. NNI promotes, offers, and sells Novo Nordisk's Ozempic®, Wegovy®, and Rybelsus® medicines throughout the United States, including in this District.

15. Defendant Mai Kaga, MD LLC is a New Jersey limited liability company operating under the alternate name of The Kaga Academy of Aesthetic & Concierge Medicine. Defendant has a business address at 830 Broad Street, Red Bank, New Jersey 07702, a registered main business address at 320 Fordham Place, Freehold, New Jersey 07728, and a registered agent/service of process address at 830 Broad Street, Suite 2, Shrewsbury, NJ 07702, all in this District.

16. Defendant sells and promotes compounded drug products that purport to contain semaglutide.

17. Defendant's semaglutide products have not been approved by the FDA ("Unapproved Compounded Drugs").

18. Defendant falsely claims or otherwise misleadingly suggests that its Unapproved Compounded Drugs are the same as or equivalent to the Ozempic®, Wegovy®, and Rybelsus® medicines.

JURISDICTION AND VENUE

19. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1338(a).

20. The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. § 1338(b).

21. Defendant is subject to personal jurisdiction in this District because Defendant is a New Jersey limited liability company and has a principal place of business in New Jersey.

22. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant resides and operates in this District, sells its compounded drug products that purport to contain semaglutide in this District, and otherwise conducts business in this District.

NOVO NORDISK'S FDA-APPROVED SEMAGLUTIDE MEDICINES AND OZEMPIC®, WEGOVY®, AND RYBELSUS® TRADEMARKS

23. Plaintiffs use the trademarks "Ozempic," "Wegovy," and "Rybelsus" to identify and promote the FDA-approved Ozempic®, Wegovy®, and Rybelsus® medicines. The Ozempic®, Wegovy®, and Rybelsus® medicines are sold and marketed in the United States by NNAS's indirect, wholly-owned subsidiary, NNI.

24. The Ozempic® medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise. The Ozempic® medicine also lowers the risk of major cardiovascular events such as stroke, heart attack, or death in adults with type 2 diabetes and known heart disease.

25. The Wegovy® medicine is indicated to reduce excess body weight and maintain weight reduction long term in adults and children aged twelve years and older with obesity, and some adults who are overweight and have weight-related medical problems, along with a reduced calorie diet and increased physical activity.

26. The Wegovy® medicine is also indicated, with a reduced calorie diet and increased physical activity, to reduce the risk of major adverse cardiovascular events such as "cardiovascular" death, heart attack, or stroke in adults with heart disease and who are either obese or overweight.

27. The Rybelsus® medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise.

28. The Ozempic®, Wegovy®, and Rybelsus® medicines have been studied in clinical trials and are FDA-approved.

29. Each of the Ozempic®, Wegovy®, and Rybelsus® medicines has a unique safety and efficacy profile which is set forth in its respective product label.

30. The Ozempic®, Wegovy®, and Rybelsus® medicines are prescription-only medicines that should be prescribed only in direct consultation with, and under the supervision of, a licensed healthcare professional.

DEFENDANT'S SALE OF UNAPPROVED COMPOUNDED DRUGS

31. Novo Nordisk has never sold its FDA-approved semaglutide medicines, Ozempic®, Wegovy®, and Rybelsus®, to Defendant for resale or redistribution.

32. Defendant markets and sells to patients Unapproved Compounded Drugs that purport to contain semaglutide.

33. The FDA has not approved Defendant's purported semaglutide products.

34. On information and belief, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them either directly to patients or to Defendant for administration or dispensing to patients.

35. The FDA defines compounding as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[2]

36. According to the FDA, "[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients."[3]

[2] U.S. FOOD & DRUG ADMIN., HUMAN DRUG COMPOUNDING (2024), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.
[3] U.S. FOOD & DRUG ADMIN., COMPOUNDING LAWS AND POLICIES (2020), https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies.

37. The FDA has further stated that it "does not verify the safety, effectiveness or quality of compounded drugs before they are marketed."[4] "Unnecessary use of compounded drugs may expose patients to potentially serious health risks."[5]

38. As the FDA has explained, "[c]ompounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness. Compounded drugs should only be used for patients whose medical needs cannot be met by an available FDA-approved drug."[6]

39. The process used to produce most "semaglutide" used in compounding is fundamentally different from the process used to produce the semaglutide in Novo Nordisk's FDA-approved medicines. Novo Nordisk manufactures the semaglutide in its medicines, pursuant to its FDA approval, in yeast cells under a closely controlled multistep process that uses recombinant DNA technology. Most compounded "semaglutide," however, uses a "semaglutide" manufactured via chemical synthesis. The fundamental differences between these processes have resulted in new impurities, higher levels of known impurities, immunogenicity concerns, and potential stability issues in tested samples of compounded "semaglutide."[7]

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[4] U.S. FOOD & DRUG ADMIN., COMPOUNDING AND THE FDA: QUESTIONS AND ANSWERS (2024), https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

[5] *Id.*

[6] U.S. FOOD & DRUG ADMIN., FDA ALERTS HEALTH CARE PROVIDERS, COMPOUNDERS AND PATIENTS OF DOSING ERRORS ASSOCIATED WITH COMPOUNDED INJECTABLE SEMAGLUTIDE PRODUCTS (2024), https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded.

[7] Morten Hach et al., *Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs*, PHARM. RSCH., Oct. 2024, available at https://pubmed.ncbi.nlm.nih.gov/39379664/.

40. The FDA has received reports of adverse events, some requiring hospitalization, related to overdoses from dosing errors associated with compounded "semaglutide" products.[8] In several instances, patients mistakenly administered five to twenty times more than the intended dose of compounded "semaglutide."[9]

41. The FDA has stated that the containers and packaging (including multidose vials and prefilled syringes) used by compounders, the varying product concentrations, and the instructions accompanying the compounded drug contribute to the potential medical errors.

42. A previous publication from the Journal of the American Pharmacists Association also highlighted errors where patients accidentally self-administered doses of compounded "semaglutide" up to ten times greater than the intended amount.[10]

43. The FDA has issued guidance on its "Concerns with Unapproved GLP-1 Drugs Used for Weight Loss," which provides that: (1) "compounded drugs are not FDA approved"; (2) use of compounded drugs containing "semaglutide" "can be risky for patients, as unapproved versions do not undergo FDA's review for safety, effectiveness and quality"; and (3) "FDA has received reports of adverse events related to compounded versions of semaglutide . . . . However, federal law does not require state-licensed pharmacies that are not outsourcing facilities to submit adverse events to FDA so it is likely that adverse events from compounded versions of these drugs are underreported."[11]

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[8] *See* U.S. FOOD & DRUG ADMIN., *supra* note 6.
[9] *Id.*
[10] Joseph E. Lambson et al., *Administration Errors of Compounded Semaglutide Reported to a Poison Control Center—Case Series,* 63 J. AM. PHARMACISTS ASS'N 5 (2023), available at https://www.japha.org/article/S1544-3191(23)00231-5/abstract.
[11] U.S. FOOD & DRUG ADMIN., FDA'S CONCERNS WITH UNAPPROVED GLP-1 DRUGS USED FOR WEIGHT LOSS (2024), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

DEFENDANT'S FALSE ADVERTISING IN CONNECTION WITH ITS SALE OF UNAPPROVED COMPOUNDED DRUGS

44. Despite the foregoing, Defendant has made false and misleading representations to patients regarding the nature of its Unapproved Compounded Drugs.

45. Defendant promotes its Unapproved Compounded Drugs by operating and advertising a health clinic, including through its website.

46. Defendant falsely advertises its Unapproved Compounded Drugs by making statements that describe the Ozempic®, Wegovy®, and Rybelsus® medicines, but that are false or misleading when in reference to Defendant's Unapproved Compounded Drugs.

47. Defendant has claimed or implied that its Unapproved Compounded Drugs have been approved by the FDA or have been reviewed by the FDA for safety, effectiveness, and quality.

48. On its website, Defendant makes false and misleading representations regarding approval by the FDA.

49. As shown below, Defendant has stated: "Thankfully, the FDA has approved semaglutide as an acceptable aide when trying to slim down your figure." *See* **Exhibit A**.

INTRODUCTION TO SEMAGLUTIDE

Weight loss can be a tumultuous journey in and of itself. You've got to count your calories, endure endless hours at the gym, and avoid all of those tasty treats – while managing this lifestyle isn't "enjoyable," it is good for you. Thankfully, the FDA has approved semaglutide as an acceptable aide when trying to slim down your figure*. At The Kaga Academy, we treat our patients with the utmost care by providing individualized attention and personalized treatment plans to achieve your desired aesthetic and health goals. The Kaga Academy is located in Red Bank, New Jersey, and conveniently sees Semaglutide patients from Colts Neck, Little Silver, Fair Haven, Rumson, and other surrounding areas. Whatever township, city, or county you're coming from, we look forward to helping you achieve your aesthetic goals from our boutique practice.

*Please remember that Semaglutide is NOT a substitute for losing weight but a way to help manage your weight.

50. Defendant has also made similarly false and misleading representations in promotional posts on social media, specifically on the Instagram platform.

51. As shown below, Defendant has stated: "We offer semaglutide, which is an FDA-approved injection once a week to help you meet your weight loss goals, otherwise known as Ozempic, Wegovy, or Rybelsus." *See* **Exhibit A**.[12]

52. Contrary to Defendant's representations, the FDA has made no such approval for Defendant's Unapproved Compounded Drugs or "semaglutide." Instead, the FDA has approved three of Novo Nordisk's medicines which contain semaglutide for the specific indications outlined in the preceding paragraphs.

[12] *See also* Dr. Mai Kaga, The Kaga Academy (@thekagaacademy), INSTAGRAM, https://www.instagram.com/p/CteWbKOMLB3/ (last visited Dec. 16, 2024).

53. Defendant's false representations mislead customers into believing, incorrectly, that the product with "semaglutide" that Defendant offers has been reviewed and approved by the FDA for safety and effectiveness.

54. Defendant also falsely claims or implies that its Unapproved Compounded Drugs contain the same semaglutide that the FDA evaluated in the context of reviewing and approving Novo Nordisk's new drug applications for the Wegovy®, Ozempic®, and Rybelsus® medicines.

55. On its website, Defendant, in promotional materials, misleadingly refers to Plaintiffs' FDA-approved medicines in the context of discussing Defendant's Unapproved Compounded Drugs. Specifically, as shown below, Defendant falsely claims that "Semaglutide – more commonly known by its brand names Wegovy, Ozempic, and Rybelsus – is helping millions of people control their hunger and change their relationship with food." *See* **Exhibit B**.

By Mai Kaga, MD

We've all heard the advice to burn more calories than we eat if we want to lose weight. But if losing weight was as easy as these people make it sound, we wouldn't have surveys showing how 95% of Americans have tried to lose weight over the last five years, and 44% actually gained weight instead.

While there's no magic solution to guarantee weight loss, there is an effective new tool in our arsenal. Semaglutide – more commonly known by its brand names Wegovy, Ozempic, and Rybelsus – is helping millions of people control their hunger and change their relationship with food.

56. Defendant has also made similarly false and misleading representations in promotional posts on social media, specifically on the Facebook platform.

57. As shown below, Defendant has stated: "We offer Semaglutide aka Ozempic/Wegovy/Rybelsus with custom weekly dosing." *See* **Exhibit B**.[13]

[13] *See also* The Kaga Academy, FACEBOOK, https://www.facebook.com/photo/?fbid=1060841202710561&set=pcb.1060841236043891 (last visited Dec. 16, 2024).

The Kaga Academy is in **Red Bank, NJ**.
June 9 ·

Our Concierge Weight Loss program is available 5 days a week with 24 hour texting with our double board certified physician, Dr. Kaga! We offer Semaglutide aka Ozempic/Wegovy/Rybelsus with custom weekly dosing.

📲You can always book your appointment or schedule a free consultation by texting 732-747-2600. Don't forget to download our app for rewards at checkout!

#sciton #clearvlaser #clearV #skincare #aesthetic #njmedspa #ozempic #weightloss

Like Comment Share

58. Defendant's representations characterizing Ozempic®, Wegovy®, and Rybelsus® as mere "brand names" falsely and misleadingly indicates that Defendant's Unapproved Compounded Drugs are a generic version of Novo Nordisk's medicines and thus have been reviewed and approved by the FDA.

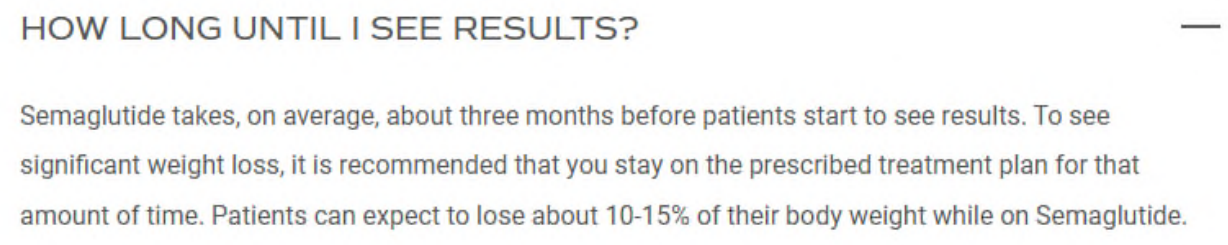
59. Novo Nordisk is not directly or indirectly supplying semaglutide to Defendant or any compounding pharmacies from which they may be sourcing their Unapproved Compounded Drugs.

60. The FDA has not reviewed the "semaglutide" allegedly in Defendant's Unapproved Compounded Drugs for safety, effectiveness, or quality, or otherwise as equivalent in safety, effectiveness, or quality to Novo Nordisk's medicines.

61. Defendant has no basis to compare the "semaglutide" allegedly in its Unapproved Compounded Drugs to Novo Nordisk's FDA-approved medications containing semaglutide.

62. Defendant further falsely claims or implies that its Unapproved Compounded Drugs have been subjected to clinical studies and trials, or have otherwise achieved therapeutic outcomes attributable to the Wegovy®, Ozempic®, and Rybelsus® medicines.

63. As shown below, Defendant in promotional materials refers to a study that on information and belief did not involve the Unapproved Compounded Drugs sold by Defendant: "Semaglutide takes, on average, about three months before patients start to see results. To see significant weight loss, it is recommended that you stay on the prescribed treatment plan for that amount of time. Patients can expect to lose about 10-15% of their body weight while on Semaglutide." *See* **Exhibit C**.



64. On information and belief, Defendant has not conducted any placebo-controlled studies on its Unapproved Compounded Drugs and is instead misleadingly referring to studies of Novo Nordisk's FDA-approved medicines to promote its Unapproved Compounded Drugs.

65. On information and belief, Defendant has engaged in these unlawful practices to attract customers and generate revenues and profits.

66. Defendant's false and misleading statements and practices are likely to cause mistake and deception in the marketplace.

67. Defendant's false and misleading marketing is also likely to expose patients to unnecessary risks. Patients who mistakenly believe Defendant to be offering Novo Nordisk's FDA-approved medicines, or equivalents thereto, are unlikely to understand the unique risks associated with, or the lack of clinical trials or testing establishing the safety and effectiveness of, Defendant's Unapproved Compounded Drugs.[14]

68. On information and belief, unless enjoined by this Court, Defendant will continue to falsely advertise its products in violation of Plaintiffs' rights.

[14] *See, e.g.*, Charlotte Huffman & Mark Smith, *Dozens Say They Lost Eyesight After Routine Surgery Using Compounded Pharmacy Drugs*, WFAA (Feb. 9, 2019), https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (reporting mistaken belief of patient taking a compounded drug that "every pill you take, every shot you take is tested"); U.S. FOOD & DRUG ADMIN., *supra* note 6 ("Compounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness.").

69. On information and belief, unless enjoined by this Court, Defendant's conduct will continue to cause mistake and deception.

FIRST CAUSE OF ACTION

Defendant's False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)

70. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

71. Defendant's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

72. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and qualities of Defendant's business practices and products, as set forth above.

73. Defendant has also engaged in other false or misleading advertising and promotion intended to assure patients that Defendant's practices are lawful. On information and belief, Defendant provides patients who purchase Defendant's Unapproved Compounded Drugs (or who Defendant is trying to persuade to purchase its drugs) information that makes false or misleading statements, including those described herein and in the exhibits hereto.

74. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

75. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

76. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

77. By reason of Defendant's acts as alleged above, Plaintiffs have suffered and will continue to suffer injuries, including injury to Plaintiffs' business reputation.

78. Plaintiffs' remedies at law are not adequate to compensate for all the injuries inflicted by Defendant.

79. Accordingly, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

80. The above-described acts of Defendant are willful.

81. Accordingly, Plaintiffs are entitled to disgorgement of defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

82. This case is exceptional, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

SECOND CAUSE OF ACTION

Unfair Competition in Violation of the Common Law

83. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

84. The above-described acts of Defendant constitute common law unfair competition.

85. The above-described acts of Defendant unfairly and wrongfully exploit Plaintiffs' goodwill and reputation.

86. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

87. Because Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief, in addition to monetary relief in the form of disgorgement of Defendant's profits and corrective advertising costs.

THIRD CAUSE OF ACTION

Unfair Competition in Violation of the New Jersey Fair Trade Act N.J.S.A. § 56:4-1 *et seq.*

88. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.

89. The New Jersey Fair Trade Act, N.J.S.A § 56:4-1 *et seq.*, prohibits merchants from appropriating a name, brand, trade-mark, reputation, or goodwill of any maker in whose product such merchant, firm, or corporation deals.

90. Defendant has violated the New Jersey Fair Trade Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and qualities of Defendant's business practices and products, as set forth above.

91. Defendant has also engaged in other false or misleading advertising and promotion intended to assure patients that Defendant's practices are lawful.

92. On information and belief, Defendant provides patients who purchase Defendant's Unapproved Compounded Drugs (or who Defendant is trying to persuade to

purchase its drugs) information that makes false or misleading statements, including those described herein and in the exhibits hereto.

93. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

94. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

95. The Court should enter preliminary and permanent injunctive relief, in addition to awarding disgorgement to Plaintiffs of Defendant's profits attributable to Defendant's false or misleading statements concerning the Unapproved Compounded Drugs.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request judgment against Defendant as follows:

1. That the Court enter a judgment against Defendant that Defendant has:

   a. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a);

   b. Engaged in unfair competition under the common law of New Jersey and violated the New Jersey Fair Trade Act, N.J.S.A. § 56:4-1 *et seq.*

2. That the Court find that each of the above acts was willful.

3. That the Court preliminarily and permanently enjoin and restrain Defendant and its agents, servants, employees, successors, and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, from:

   a. advertising, stating, or suggesting that any Unapproved Compounded Drugs, including any Unapproved Compounded Drugs that either are available, directly or indirectly, from or through Defendant or the use of which or access to which is facilitated by, or with the involvement of, Defendant:

i. are, or contain, genuine or authentic Novo Nordisk Ozempic®, Wegovy®, or Rybelsus® medicines;

ii. are sponsored by or associated with Novo Nordisk;

iii. are approved by the FDA; have been reviewed by the FDA for safety, effectiveness, or quality; or have been demonstrated to the FDA to be safe or effective for their intended use;

iv. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes, including but not limited to by relying on or making reference to clinical trial results for Novo Nordisk's medicines;

v. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes similar or identical to Novo Nordisk's medicines or are interchangeable with or equivalent to genuine Novo Nordisk medicines;

vi. are associated or connected in any way with Novo Nordisk or Novo Nordisk's medicines; or

vii. contain any ingredient (including semaglutide) that is supplied by Novo Nordisk, is approved by the FDA, or is the same as any ingredient in any Novo Nordisk medicine; and/or

b. engaging in any unfair competition with Plaintiffs.

4. That the Court require Defendant to disclose conspicuously and prominently in any public-facing materials for any Unapproved Compounded Drugs, including all advertising, marketing, and promotional materials, that: (a) the Unapproved Compounded Drugs are compounded drugs that have not been approved by the FDA; have not been reviewed by the

FDA for safety, effectiveness, or quality; and have not been demonstrated to the FDA to be safe or effective for their intended use; (b) the processes by which the compounded drugs are manufactured have not been reviewed by the FDA; and (c) FDA-approved medicines containing semaglutide are available.

5. That the Court award Plaintiffs monetary relief in the form of disgorgement of Defendant's profits for Defendant's false advertising and unfair competition and that this monetary relief be trebled due to Defendant's willfulness, in accordance with 15 U.S.C. § 1117 and any applicable state laws.

6. That the Court order Defendant to account for and disgorge to Plaintiffs all amounts by which Defendant has been unjustly enriched by reason of Defendant's unlawful actions.

7. That the Court award Plaintiffs punitive damages by reason of Defendant's willful unlawful actions.

8. That the Court award Plaintiffs pre-judgment and post-judgment interest on all damages.

9. That the Court award Plaintiffs their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117 and any other applicable provision of law.

10. That the Court award Plaintiffs the costs of suit incurred herein.

11. That the Court award such other or further relief as the Court may deem just and proper.

Dated: January 10, 2025
Newark, New Jersey

Respectfully submitted,

s/ Christopher Walsh
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